

*REMARKS/ARGUMENTS**The Pending Claims*

Claims 1-17 and 69-73 are pending. Claims 1-17 and 69-73 are directed to a tricalcium phosphate composition. Reconsideration of the pending claims is respectfully requested.

*The Amendments to the Claims*

Claims 18-68 have been canceled in view of the finality of the restriction requirement and without prejudice to Applicant's right to pursue the inventions of these canceled claims in a divisional application. No new matter has been added by way of these amendments.

*The Summary of the Office Action*

Claims 1-3, 5, 6, 12-14, and 69-73 stand rejected under 35 U.S.C. § 102(b) as anticipated by Tanaka et al. (i.e., U.S. Patent 6,441,073).

Claims 15-17 apparently stand rejected under 35 U.S.C. § 103(a) as obvious over Tanaka et al. in view of Dalal et al. (i.e., U.S. Patent 6,949,251). Additionally claims 8-11 apparently stand rejected under 35 U.S.C. § 103(a) as obvious over Tanaka et al. in view of Kijima et al. (i.e., U.S. Patent 5,185,177). Although the Office Action nowhere indicates that the statutory basis for the rejections over Dalal et al. and Kijima et al. is 35 U.S.C. § 103(a), Applicant presumes that a rejection under this section was intended based on the discussion of the cited references. If Applicant's interpretation of the Office Action is incorrect, Applicant respectfully requests clarification of the rejection in the next Office Action.

Claims 4 and 7 are indicated in the Office Action Summary as being rejected, but no specific rejection is set forth in the Office Action. Applicant respectfully requests that the Office set forth its statutory basis for rejecting claims 4 and 7, or alternatively confirm that claims 4 and 7 have been allowed.

*The Anticipation Rejection*

The anticipation rejection is respectfully traversed.

As a preliminary matter, Applicant notes that Tanaka et al. published on August 27, 2002, less than one year prior to Applicant's filing date of August 6, 2003. Accordingly, Tanaka et al. is not prior art under 35 U.S.C. § 102(b). For this reason alone, the rejection should be withdrawn.

In any event, Tanaka et al. fails to disclose particulate tricalcium phosphate having an average particle size of about 5  $\mu\text{m}$  or less, an average crystal size of about 250 nm or less and a surface area of about 20  $\text{m}^2/\text{g}$  or greater as recited by the pending claims. Tanaka et al. is directed to a biomaterial comprising particulate calcium phosphate, such as a tricalcium phosphate, which is compounded with a copolymer of lactic acid, glycolic acid, and caprolactone. Tanaka et al. teaches that tricalcium phosphate is preferred because it is readily absorbed in vivo. However Tanaka et al., like Tofighi et al. cited in the Office Action dated December 26, 2006, teaches that tricalcium phosphate is limited in application because "its mechanical strength is weak" and because "it has little ability of giving a shape to a bone implantation material." See Col. 2, ll. 10-22. To solve this problem, Tanaka et al. teaches that the tricalcium phosphate material is compounded with a polymer which provides the necessary strength and rigidity. See, e.g., Col. 2, ll. 23-25. The relative amounts of the lactic acid, glycolic acid and caprolactone affect the rigidity of the resulting copolymer, see, e.g., Col. 7, ll. 5-12, 23-26, and the strength and rigidity of the compounded material depends on the relative amount of copolymer and calcium phosphate. See, e.g., Col. 8, ll. 36-52.

While Tanaka et al. teaches that the average particle size is preferably 0.1 to 200 microns, Tanaka et al. is silent with respect to the crystal size and surface area of the calcium phosphate material that is to be combined with the copolymer. The Office Action asserts that the surface area recited by the pending claims would "necessarily be present" in the tricalcium phosphate material taught by Tanaka et al. However this is not the case. Tanaka et al. teaches that the mixing ratio of tricalcium phosphate to copolymer preferably is 1:0.1 to 1:2. One of ordinary skill in the art will appreciate that in order to achieve such high solids loadings, the tricalcium phosphate surface area would have to be relatively low so that the polymer can wet the particle surfaces and form a continuous phase. At high surface areas,

polymer loading will decrease because more polymer will be required to wet the surface and not be available to form a continuous phase. In particular the surface area is likely to be lower than  $20 \text{ m}^2/\text{g}$  and typically on the order of  $\sim 1 \text{ m}^2/\text{g}$ . This is further evidenced by the fact that Tanaka et al. teaches that the calcium phosphate particles should be sintered prior to compounding with the copolymer. See, e.g., Col. 7, l. 65 to Col. 8, l. 8. One of ordinary skill in the art will appreciate that the purpose of sintering in this context is to *lower* the surface area so as to achieve improved compounding and loading. Moreover, the mere fact that the calcium phosphate particles taught by Tanaka et al. must be compounded with a copolymer in order to achieve necessary strength is evidence that the calcium phosphate particles of Tanaka et al. are not capable of being consolidated to form a TCP article having a compressive strength of about 50 MPa or greater, as recited by the pending claims.

The Office Action asserts that the claimed surface area would “necessarily be present” in the tricalcium phosphate material of Tanaka et al. because the particle size of the material taught by Tanaka et al. is “similar” and because the tricalcium phosphate material of Tanaka et al. “is made by the same process of being sintered at a similar temperature as the instantly claimed sintering temperature.” One of ordinary skill in the art will appreciate that mere similarity of particle size is no indication whatsoever of the crystal size and surface area that a material will have, aside from the obvious fact that the crystal size of a particle cannot exceed the particle size. Indeed particles of the same particle size can have very different crystal sizes and/or surface areas. Moreover, although Tanaka et al. teaches that the particulate calcium phosphate is preferably sintered before compounding with a copolymer purportedly “resulting in a high density” of the tricalcium phosphate, there is no indication that such densification could result in a densified article having a density that is 60% of the theoretical density or greater, as recited by the pending claims.

Applicants have discovered that consolidated TCP articles having surprisingly high compressive strength can be formed from TCP compositions through careful control of the particle size, crystal size, and surface area of the precursor TCP composition. This is not taught or recognized by Tanaka et al. To the contrary, Tanaka et al. teaches away from the invention recited in the pending claims by teaching that tricalcium phosphate material can only achieve desirably strength and rigidity when it is compounded with a copolymer as taught by Tanaka et al.

Since Tanaka et al. fails to teach each and every element of the invention recited in the pending claims, the anticipation rejection is improper and should be withdrawn.

*The Obviousness Rejections*

The obviousness rejections are respectfully traversed.

Dalal et al. fails to cure the deficiencies of Tanaka et al. As discussed in Applicant's previous response to the Office Action dated December 26, 2006, Dalal et al. is directed to a  $\beta$ -TCP composition and the use thereof to prepare porous  $\beta$ -TCP granules which can be combined with a binder to form a moldable putty composition. Nothing in Dalal et al. teaches or suggests a TCP composition having the crystal size, particle size, or surface area recited by the pending claims. In addition, nothing in Dalal et al. teaches or suggests the use of that composition to form a consolidated TCP article having a compressive strength of about 50 MPa or greater, as recited by the pending claims. Thus, even if one of ordinary skill in the art were motivated to combine the teachings of Tanaka et al. with Dalal et al., which they would not be, such combination would not provide a TCP composition having the particle size, crystal size, and surface area recited in the pending claims.

Similarly, Kijima et al. fails to cure the deficiencies of Tanaka et al. Kijima et al. is directed to a sintered body of zirconia having a porous, sintered coating comprising a mixture of zirconia and tricalcium phosphate. Nothing in Kijima et al. teaches or suggests a TCP composition having the crystal size, particle size, or surface area recited by the pending claims. In addition, nothing in Kijima et al. teaches or suggests the use of that composition to form a consolidated TCP article having a compressive strength of about 50 MPa or greater, as recited by the pending claims. Thus, even if one of ordinary skill in the art were motivated to combine the teachings of Tanaka et al. with Kijima et al., which they would not be, such combination would not provide a TCP composition having the particle size, crystal size, and surface area recited in the pending claims.

For all of these reasons, the combination of Tanaka et al. with Dalal et al. and/or Kijima al. fails to teach or suggest each and every element of the invention recited in the pending claims. Accordingly, the obviousness rejections are improper and should be withdrawn.

*Conclusion*

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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Date: November 27, 2007